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once a day for 2 to 3 days beyond cessation of clinical signs of disease up to a maximum of 30 days.

- (ii) *Indications for use*. For management of diseases in dogs associated with bacteria susceptible to difloxacin.
- (iii) *Limitations*. Federal law prohibits the extra-label use of this drug in food-producing animals. Federal law restricts this drug to use by or on the order of a licensed veterinarian.
 - (2) [Reserved]

[63 FR 8123, Feb. 18, 1998, as amended at 75 FR 10165, Mar. 5, 2010]

§ 520.666 Dirlotapide.

- (a) Specifications. Each milliliter (mL) of solution contains 5 milligrams (mg) dirlotapide.
- (b) Sponsor. See No. 000069 in \$510.600(c) of this chapter.
- (c) Conditions of use in dogs—(1) Amount. The initial dosage is 0.01 mL/kg (0.0045 mL/lb) body weight for the first 14 days. After the first 14 days of treatment, the dose volume is doubled to 0.02 mL/kg (0.009 mL/lb) body weight for the next 14 days (days 15 to 28 of treatment). Dogs should be weighed monthly and the dose volume adjusted every month, as necessary, to maintain a target percent weight loss until the desired weight is achieved.
- (2) Indications for use. For the management of obesity.
- (3) *Limitations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[72 FR 263, Jan. 4, 2007]

§ 520.763 Dithiazanine iodide oral dosage forms.

§520.763a Dithiazanine iodide tablets.

- (a) [Reserved]
- (b) Specifications. Dithiazanine iodide tablets contain 10 milligrams, 50 milligrams, 100 milligrams, or 200 milligrams of dithiazanine iodide in each tablet.
- (c) Sponsor. See No. 054628 in \$510.600(c) of this chapter.
- (d) Conditions of use. (1) The tablets are administered orally to dogs immediately after feeding using the following dosage schedule for various parasite infestations:

	Milligrams per pound of body weight	Length of treatment—days
Large roundworms (<i>Toxocara</i> canis, <i>Toxascaris</i> leonina) Hookworms (<i>Ancylostoma</i>	10	3–5
caninum, Uncinaria		
stenocephala)	10	7
Whipworms (Trichuris vulpis)	10	
Strongyloides (Strongyloides canis, Strongyloides		
stercoralis)	10	10–12
Heartworm microfilariae		
(Dirofilaria immitus)	3–5	7–10

Note: Treatment with dithiazanine iodide for heartworm microfilariae should follow 6 weeks after therapy for adult worms.

- (2) The drug is contraindicated in animals sensitive to dithiazanine iodide and should be used cautiously, if at all, in dogs with reduced renal function.
- (3) Federal law restricts this drug to use by or on the order of a licensed veterinarian.
- (e) Use for treating dogs for large roundworms, hookworms, whipworms, and strongyloides as provided for in this section has been NAS/NRC reviewed and deemed effective. Applications for these uses need not include effectiveness data as specified by §514.111 of this chapter, but may require bioequivalency and safety information.

[40 FR 13838, Mar. 27, 1975, as amended at 47 FR 51564, Nov. 16, 1982; 48 FR 32342, July 15, 1983; 53 FR 40727, Oct. 18, 1988; 62 FR 35076, June 30, 1997; 78 FR 21059, Apr. 9, 2013]

§ 520.763b Dithiazanine iodide powder.

- (a) [Reserved]
- (b) Specifications. Dithiazanine iodide powder contains 200 milligrams of dithiazanine iodide per level standard tablespoon.
- (c) Sponsor. See No. 054628 in \$510.600(c) of this chapter.
- (d) Conditions of use. (1) Dithiazanine iodide powder is administered to dogs by mixing the proper dosage in the dog's food, using the following dosage schedule for various parasite infestations:

	Milligrams per pound of body weight	Length of treatment—days
Large roundworms (Toxocara canis, Toxascaris leonina)	10	3–5